

REMARKS

Entry of the foregoing and further and favorable reconsideration of the subject application in light of the following remarks, pursuant to and consistent with 37 C.F.R. § 1.112, are respectfully requested.

By the foregoing amendment, the title of the application has been amended as requested by the Examiner. Claims 1-4 have been amended to further clarify Applicants' invention, and claim 5 has been added. Support for claim 5 can be found on pages 23 and 42 of the specification. No new matter has been added.

The rejection of claim 2 under 35 U.S.C. § 112, second paragraph, is moot in view of the amendment to the claim.

Claims 1 and 2 have been rejected under 35 U.S.C. § 102(e) as allegedly being anticipated by Chen et al. (U.S. Patent No. 6,200,780). Applicants respectfully traverse this rejection.

Chen et al. identifies the protein encoded by SEQ ID NO:1 as being an interferon-epsilon protein designated "PRO655" and distinguish this interferon-epsilon from beta- and alpha-interferons (see e.g., columns 1-3 of Chen et al.). In particular, Chen et al. discloses that the interferon-epsilon is a "new and distinct type I interferon" (see e.g., column 1, lines 10-14 of Chen et al.) and that "despite similarities in their binding properties, the biological responses stimulated by type I interferons are significantly different" from each other (see e.g., column 3, lines 4-6 of Chen et al.). Thus, Chen et al. teaches that the protein encoded by SEQ ID NO:1 is an interferon-epsilon that is distinguished from beta-interferon and other type I interferons, and do not teach or suggest the claimed interferon-beta2.

In view of the above, Chen et al. does not teach each and every element of the claimed invention and thus cannot anticipate the claimed invention.

Accordingly, applicants request withdrawal of this rejection.

Claims 3 and 4 have been rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Chen et al. (U.S. Patent No. 6,200,780) in view of Polman et al. (*J. Neurol. Neurosurg. Psychiatry*, 67:561-6, 1999). Applicants respectfully traverse this rejection.

A:
A:
Re:
Reply: The Examiner alleges that Chen et al. teaches a protein identical to Applicants' claimed interferon-beta2; that interferon-epsilon is useful for upregulating the immune system; and that it is a type I interferon. However, the Examiner notes that Chen et al. fails to teach that interferon-epsilon can be used to treat multiple sclerosis ("MS"). The Examiner also alleges that Polman et al. teaches that interferon-beta is useful for treating MS and is a type I interferon, and further alleges that type I interferons use the same receptor, have comparable effects, and have a high degree of homology. Thus, the Examiner concludes that it would have been obvious for the skilled artisan to combine the teachings of Chen et al. with Polman et al. to use interferon-epsilon to treat MS. Applicants respectfully disagree.

The differences between the claimed invention and the polypeptide of Chen et al. have been discussed above. Chen et al. teaches away from the claimed interferon-beta2 by distinguishing their interferon-epsilon from other type I interferons, including beta-interferons.

Polmann et al. states that IFN- α and IFN- β use the same receptor (see p. 561 second para.), not that "type I interferons use the same receptor" as alleged by the Examiner. This reference does not teach or suggest that all type I IFNs (including IFN- ϵ) use the same receptor.

A:
A:
Re:
Reply: Furthermore, Polman et al. does not teach nor suggest that type I interferons in general would be useful for treating MS. Polman et al., in reviewing clinical evidence of interferon-beta 1a and 1b used in the treatment of MS patients, merely teaches that the evidence indicates that interferon-beta 1a and 1b may be beneficial for treatment of MS in specific cases (for each interferon) and, notably, discusses the differences in clinical response with regard to these two type I interferons (see e.g., page 561, column 1, para. 4 and page 563, column 2, para. 3 of Polmann et al.). There is no mention of the claimed IFN- β 2.

Thus, there is no suggestion or motivation in either reference to lead the skilled artisan to combine these references to arrive at the claimed invention. Chen et al. teaches that IFN- ϵ is distinct from IFN- α and IFN- β (IFN- β 2) and Polmann et al. teaches that IFN- β 1a and IFN- β 1b may be beneficial for treatment of MS in specific cases.

A:
A:
Re:
Reply: One skilled in the art would have known that: i) the ways that type 1 interferons interact with the type 1 receptor are distinguishable from each other (e.g., type I interferons do not have the same binding affinity for the type I receptor); ii) they do not induce the same genes; and iii) notably, their clinical response differs (see, e.g., Cirelli et al., Arnason et al.,

Panitch, and Austims Research Group, attached hereto). For example, interferon-beta 1a and 1b have been shown to have beneficial effects for the treatment of MS (see, e.g., attached references Cirelli et al., Arnason et al., Panitch), whereas another type I interferon, interferon-alpha was shown to have no effect on the symptoms or progress of MS (see, e.g., attached references Panitch and Austims Research Group).

Thus, in view of the above, Applicants assert that it would not have been obvious to combine the teachings of Chen et al. with Polman et. to use interferon-epsilon to treat MS. Thus, withdrawal of this rejection is respectfully requested.

In view of the foregoing, further and favorable action in the form of a Notice of Allowance is believed to be next in order. Such action is earnestly solicited.

In the event that there are any questions relating to this application, it would be appreciated if the Examiner would telephone the undersigned attorney or agent concerning such questions so that prosecution of this application may be expedited.

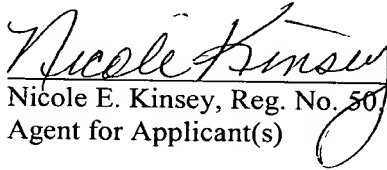
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Reply Dated December 15, 2003
Reply to Office Action of August 14, 2003

The Commissioner is hereby authorized to charge any fees associated with this response or credit any overpayment to Deposit Account No. 13-3402.

Respectfully submitted,



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